

REMARKS

The Office Action mailed October 24, 2000, has been received and its contents carefully noted. In order to advance prosecution, the specification has been editorially amended, a new abstract has been added as new page 36 of the Application and has been reproduced on a separate sheet attached hereto, claims 1-14 have been canceled, and new claims 15-37 have been added to the Application. An additional claim fee of \$54 is attached to cover the cost of three total claims in excess of 20. Should any additional fee be deemed due, however, please charge the same to Deposit Account No. 22-0261 and advise us accordingly.

New claims 15 and 16 find support in claims 1 and 3, and in the specification on page 14, line 8, for "plastic fluid".

New claims 17-21 find support in claims 4-8.

New claims 22 and 23 find support in claims 2 and 3, and in the specification on page 14, line 8, for "plastic fluid".

New claims 24-28 find support in claims 4-8 (and 10-14).

New claims 29-37 find support in claims 1-8 and in the specification on page 4, line 13, for "enteric".

Claims 15-37 are now pending in the Application and are submitted to be in allowable condition.

The objection to claims 1-14 is moot in view of cancellation of these claims.

Applicants wish to point out that the compositions of present invention include not only the simple substance, glucan, but also mannan, chitin, protein, etc. (see page 11, lines 4-8). The Examiner, however, has focused only on glucan and has rejected the present invention based on the prior art including Provonchee et al., Shank, and James et al.

The rejection of claims 1, 2, 4, 6, 7, 10, 12, and 13 under 35 U.S.C. §102 as anticipated by Provonchee et al. (US 4,774,093) is moot in view of cancellation of these claims and is respectfully traversed for new claims 15-37.

Applicants do not agree that Provonchee et al. anticipate these claims because the disclosure of Provonchee et al. does not meet Applicants' new claims which recite, "... a coating agent **which is a plastic fluid**, ...[emphasis added]", (see the specification, page 14, line 8, "plastic fluid").

Provonchee et al. disclose a polysaccharide composition of the gel-forming beta-1,3-glucan type and methods of preparing and using said polysaccharide composition. The disclosure of Provonchee et al. teaches substances which are **pseudo-plastic fluids** as observed in general polymers. The present invention is distinguishable in that Applicants' coating agent is **a plastic fluid**, i.e., a non-Bingham body, such as ketchup (see the specification, page 14, line 8). This distinction is submitted to be well known in the art.

References:

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|-------------------------------------|-------------------|
| (a) Newton fluid: | water, oil, air |
| (b) non-Newton fluid: Bingham fluid | asphalt, paint |
| pseudo-plastic fluid | polymer solution, |

	starch paste
dilatant fluid	starch+water, mixture of water and sand

Therefore, the coating agent of the present invention is submitted to be distinguishable and essentially different from the substances employed by Provonchee et al.

Additional distinguishing features include (1) - (4) which follow:

(1) The disclosure of Provonchee et al. teaches gel formability. The present invention is distinguishable in that gel formability is not observed and is not desired. Applicants' coating agent is **a plastic fluid**, i.e., a non-Bingham body, such as ketchup (see the specification, page 14, line 8).

(2) The disclosure of Provonchee et al. teaches substances which are normal chain polysaccharides, such as curdlan, which are soluble in an alkaline aqueous medium. The present invention is distinguishable in that Applicants' coating agent is not soluble in an alkaline aqueous medium.

(3) The disclosure of Provonchee et al. teaches substances which are pH dependent , namely, of the alkaline soluble type, so that release of pharmaceuticals encapsulated by the substances of Provonchee et al. require an alkaline medium. The present invention is distinguishable in that Applicants' coating agent is pH-independent and able to dissolve under preselected dissolution times (see the data presented in Applicants' Figure 2).

(4) The disclosure of Provonchee et al. teaches substances having oxygen permeability which can be surmised from the disclosed use for contact lenses which require oxygen permeability. The present invention is distinguishable in that Applicants' coating agent has

oxygen barrier ability, i.e., the level of oxygen permeability is extremely low (see Applicants' specification page 28 and 29, Example 11).

The rejection of claims 1, 2, 4, 6, 7, 10, 12, and 13 under 35 U.S.C. §102 as anticipated by Shank (US 4,001,408) is moot in view of cancellation of these claims and is respectfully traversed for new claims 15-37.

Applicants do not agree that Shank anticipates these claims because the disclosure of Shank does not meet Applicants' claims. The coating agent, coated material, and coating film of the present invention are distinguishable and essentially different from the substances employed and the coating result obtained by Shank for the reasons which follow.

Shank discloses a product, such as a drug, condiment or vitamin, encapsulated within biological capsules provided by microorganisms, such as yeast. The disclosure of Shank teaches microencapsulation of substances to provide microcapsules. Microencapsulation is a technique for enclosing substances in individual cells. The encapsulated substances in Shank are fat-soluble, i.e., liquids, such as pigments. The appearance of the products after microencapsulation is that of a grain or a powder.

The present invention is distinguishable as relating to the technique of forming films of a coating agent comprising yeast cell wall fractions onto a substance. Film formation is submitted to be essentially different from encapsulation as an artisan would readily appreciate.

Further, the substances to be coated in the present invention are solids and it does not matter whether the substances are fat-soluble or water-soluble. The appearance of Applicants' coated material is a fine particle, a granule, a tablet, or the like. Therefore, the coating agent,

coated material, and coating film of the present invention are distinguishable and essentially different from the substances employed and the coating result obtained by Shank.

The rejection of claims 1-14 under 35 U.S.C. §103 as being unpatentably obvious over Provonchee et al. in view of Jamas et al. (US 6,020,324) is moot in view of cancellation of claims 1-14 and is respectfully traversed for new claims 15-37. The Examiner acknowledges that Provonchee et al. do not disclose a plasticizer for which reason the Examiner relies on Jamas et al.

Applicants do not agree that the combined disclosures of Provonchee et al. and Jamas et al. set out a *prima facie* case of obviousness against new claims 15-37 (1) because Applicants traverse the combination of Provonchee et al. and James et al. and (2) because - even if combined - the combined disclosures do not meet Applicants' claims.

Jamas et al. relates to a composition and method utilizing yeast glucan as a dietary additive. Jamas et al. relates to compositions useful for treatment of dietary disorders. Though Jamas et al. refer to coating material and plasticizer, these are mentioned only in the context of making tablets out of glucan compositions for oral administration. Jamas et al. do not suggest that glucan is a coating agent.

The present invention is distinguishable as teaching supplemental materials to protect useful substances by coating a film thereon. Applicants are not seeking to provide compositions useful for treatment of dietary disorders as is James et al. which employs glucan as an active ingredient for reduction of the level of serum cholestetrol, for example.

Furthermore, James et al. does not teach or suggest dissolution control provided by a coating provided on a coated material unlike the present invention where there is a concrete disclosure about designing dissolution control by additives, such as agar or glycerol.

Applicants' respectfully submit that Jamas et al. has nothing to do with the present invention and respectfully traverse the combination of Provonchee et al. and Jamas et al. as finding no suggestion in either reference.

Moreover, the composition of the product of the present invention is different from the disclosed composition of Provonchee et al. and has nothing to do with making tablets by adding plasticizer as taught by Jamas et al. Thus, if, for the sake of argument, the combination of the disclosures of Provonchee et al. and James et al. is made, Applicants submit that the coating agent, coated material, and coating film of the present invention would not result Applicants coating agent, coated material, and coating film are submitted to be distinguishable and essentially different from those possible from any such combination for the reasons given in the foregoing.

The rejection of claims 1-14 under 35 U.S.C. §103 as being unpatentably obvious over Shank (US 4,001,480) in view of Jamas et al. (US 6,020,324) is moot in view of cancellation of claims 1-14 and is respectfully traversed for new claims 15-37. The Examiner acknowledges that Shank does not disclose a plasticizer for which reason the Examiner relies on Jamas et al.

Applicants do not agree that the combined disclosures of Shank and Jamas et al. set out a *prima facie* case of obviousness against new claims 15-37 (1) because Applicants traverse the

combination of Shank and James et al. and (2) because - even if combined - the combined disclosures do not meet Applicants' claims.

As discussed in the foregoing, Jamas et al. relates to a composition and method utilizing yeast glucan as a dietary additive. Jamas et al. relates to compositions useful for treatment of dietary disorders. Though Jamas et al. refer to coating material and plasticizer, these are mentioned only in the context of making tablets out of glucan compositions for oral administration. Jamas et al. do not suggest that glucan is a coating agent.

The present invention is distinguishable as teaching supplemental materials to protect useful substances by coating a film thereon. Applicants are not seeking to provide compositions useful for treatment of dietary disorders as is James et al. which employs glucan as an active ingredient for reduction of the level of serum cholestetrol, for example.

Furthermore, James et al. does not teach or suggest dissolution control provided by a coating provided on a coated material unlike the present invention where there is a concrete disclosure about designing dissolution control by additives, such as agar or glycerol.

Applicants' respectfully submit that Jamas et al. has nothing to do with the present invention and respectfully traverse the combination of Shank and Jamas et al. as finding no suggestion in either reference.

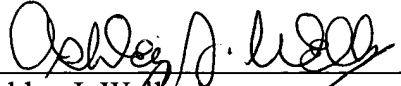
Moreover, the composition of the product of the present invention is different from the disclosed composition of Shank and has nothing to do with making tablets by adding plasticizer as taught by Jamas et al. That is, if an artisan were to change the composition and the methods disclosed by Shank to a composition including plasticizer and a method to make tablets as disclosed by Jamas et al., the product of Shank would be presumed to be only a substance

consisting of a group of microcapsules. Thus, if, for the sake of argument, the combination of the disclosures of Shank and James et al. is made, Applicants submit that the coating agent, coated material, and coating film of the present invention would not result. Applicants coating agent, coated material, and coating film are submitted to be distinguishable and essentially different from those possible from any such combination for the reasons given in the foregoing.

In view of the foregoing amendments and remarks, it is requested that the rejections of record be reconsidered and withdrawn, that new claims 15-37 be allowed, and that the Application be found to be in allowable condition.

Should the Examiner not find the Application to be in allowable condition or believe that a conference would be of value in expediting the prosecution of the Application, Applicants request that the Examiner telephone undersigned Counsel to discuss the case and afford Applicants an opportunity to submit any Supplemental Amendment that might advance prosecution and place the Application in allowable condition.

Respectfully submitted,


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